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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/924,732	08/08/01	VIANELLO	P 328/US

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EXAMINER	
FORD, J	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/924732	Applicant(s) Vianello et al
	Examiner Jim Ford	Group Art Unit 1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1 - - 10 is/are pending in the application.

Of the above claim(s) 9 - - 10 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 - - 8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The claims in the application are claims 1--18.

Claims 1, 5 rejected under 35 U.S.C. 112, 1st and 2nd paragraph.

In line 3, no knows what the pro-drug would be. What compound, fed to what mammal, would result in this compound?

Near the top of page 69 one finds heteroaryl ring with one to three heteroatoms selected from O, S, or N. What heteroatoms are located where. Each combination is a different ring with a separate classification and separate search. Thiazines would control the classification and search before the formula I oxazine here. Heteroaryl is a hugh area of chemistry that is hidden in the language of the claim, that requires specific conception by the reader. Adjacent O/O; O/S or S/S combinations claimed here are too unstable to be made. What is the source of the starting materials? Applicants claim compounds that have not, yet, been made. Note, In re Wiggins, 179 USPQ 421, 423.

In claims 1 and 2, and 5 and 6 and 9 and 10, what is the purpose of the proviso statement at the end of the claim? Prior art?

Claim 1, 5 is rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The R2 definition refers to a heterocyclic; it reads on heterocyclic rings, without indicating what the heterocyclic ring is, that is being claimed.

The heterocyclic term is not acceptable as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

The heterocyclic term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

Exactly what ring is being claimed must be set forth in the claim.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. V. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at page 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic grounds for rejecting claims under 35 U.S.C. 112; first is that the language used is not precise enough to provide a clear-cut indication of the scope of the subject matter embraced by claim; this ground finds it basis in the second paragraph of section 112; second is that the language is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heterocyclic variable is not believed to meet the requirements of 35 U.S.C. 112, first and second paragraph.

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is so broad that cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.;

The written description is considered inadequate here in the specification. Conception should not be the role of the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability; In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazines, triazines, Oxathiazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

Conception of what the intended heterocyclic ring may be, should not be left to the reader.

One needs to know exactly wherein the ring the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1,3,5, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heterocyclic term applied by applicant, has no idea where the hetero atoms are in this unknown ring.

Not all heterocyclic ring have been shown to be producible, as stable at room temperature. What is the source of the starting material? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic definition presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification? Even any combination of atoms, selected from the group consisting of O, S, or N, rests specific conception with the reader. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible heterocyclic ring is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed.

The utility here is pharmaceutical. Declarations of unexpected results are often presented in this art. Applicants breadth of heterocyclic produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heterocyclic expressions in claim 1 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which would fall within the claim language.

In the chemical compound area, in which applicant now claims, one must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes other from making, using, or selling that compound 17/20 years. Therefore, one must know what compound is being claimed.

The written description is considered inadequate herein the specification. Conception should not be the role of the reader. Applicant should, in return for a 17/20 monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability. In re Kirk, 153 U.S.P.Q. 48 at page 53.

The claims measure the invention: United Carbon Co. V. Binney & Smith Co. 55 U.S.P.Q 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockhead Aircraft Corp. vs. United States, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

Claim 8 is rejected under 35 U.S.C. 112, 1st and 2nd paragraph as no one knows what the prodrug is in line 2. All of these species in one claim, cannot be searched.

The utility in claim 9 cannot be accepted as relating to the real World of Commerce.

Claims 9--18 are restricted out under the provisions of MPEP 806.05(h). Restricting out the method claims is proper where it can be shown that the compounds can be used for more than one purpose. The claims act as evidence claims that the compounds may be used for more than one use.

If applicants wish they may elect one specific, understandable utility to be examined here, if it is of the same scope of the compound genus.

Claim 9 does not appear to relate to the real world of commerce, Brenner Comr. Pats. v. Manson, (USSC 1966) 383 US 519, 148 U.S.P.Q. 689. The court stated that Congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing, reasoning the patent system is related to the world of commerce, rather than the realm of philosophy ibid., 148 U.S.P.Q. at 696. Claim 9 is not specific enough to a particular disease in the real world.

Claims 4 and 8 are impossible, each species is a separate search question. I have no way of reporting on the patentability of claims 4 and 8. They are not searchable in the time limits provides. Claims 4 and 8 do not comply with 37 CFR 1.141(a) that each species be in a different claim.

There are 4 pages of species in these claims.

Claims 4 and 8 do not comply with 37 CFR 1.141(a). The Rule calls for the species to be in different claims and be limited to a reasonable number, which is not the case here. Each species is an individual search. Applicants are avoiding proper fees for species by grouping them all in one claim.

There is a different claim requirement in Rule 1.141(a). A reasonable number of species may be claimed in different claims. Each species has to bre in a different claim. The fee for each dependent claim is $18.00. The cost to search each distinct species is $45.00. The USPTO is losing money on the search here, when this large number of species, which have to be considered individually, are grouped into one claim.

Issenstead v. Watson, (DCDC 1957) 157 F. Supp. 7, 115 U.S.P.Q. 408 Schindler v. Comr. of Pats. (DCDC 1967) 269 F.Supp. 630, 155 U.S.P.Q. 838. Noted where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Radoev v. Brenner, Feguson, (POBA 1957) 117 U.S.P.Q. 209.

The Board of Appeals and the C.C.P.A. have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of human use and require proof thereof, when such use is a medical nature for the treatment of a serious disease. Ex parte Moore et al. (POBA 1960) 128 U.S.P.Q. 8; In re Citron, (C.C.P.A. 1964 325 F.2D 248, 139 U.S.P.Q. 516; In re Hartop et al., (C.C.P.A. 1962) 311 F.2d 249, 135 U.S.P.Q. 419.

In 1964, when I started as an Examiner, 37 CFR 1.141 provided for no more than 5 species in a claim as each has to be separately searched, as there is no genus, this was changed to a reasonable number. Claims 4 and 8 do not contain a reasonable number of species.

Any claim not specifically rejected, or withdrawn, is rejected as being dependent on a rejected claim, therefore, not allowable.

J. Ford:jmr

Oct. 22, 2001

JOHN M. FORD
PRIMARY EXAMINER